

**Emergency Rule**  
LSA Document #18-362(E)

**DIGEST**

Temporarily amends [856 IAC 3](#) to add requirements for licensure and operation of third party logistics providers. Statutory authority: [IC 25-26-14-32](#). Effective 30 days after filing with the Publisher.

**SECTION 1. This document establishes requirements for licensure and operation of third party logistics providers.**

**SECTION 2. All terms which are defined in [IC 25-26-14](#) shall have the same definitions when used in this document.**

**SECTION 3. The following fees apply to an applicant for licensure as a third party logistics provider:**

<b>(1) Application for licensure as a third party logistics provider</b>	<b>\$100</b>
<b>(2) Renewal of licensure</b>	<b>\$100</b>
<b>(3) Controlled substances registration</b>	<b>\$100</b>

**SECTION 4. Third party logistics provider licenses shall expire on September 30 of each even-numbered year.**

**SECTION 5. (a) An application for licensure as a third party logistics provider shall be made on a form approved by the board and accompanied by any fees required by SECTION 3 of this document.**

**(b) An applicant who is physically located in Indiana shall provide a copy of an inspection report, as required by [IC 25-26-14-14.2](#), from a third party inspection provider, dated not more than one (1) year before the date of application for a license, with their application for licensure.**

**(c) An applicant who is not physically located in Indiana shall provide the following with their application for licensure:**

- (1) Documentation that the out-of-state third party logistics provider is licensed as a third party logistics provider in the state where the third party logistics provider is located; or, is licensed by the federal Food and Drug Administration. Verification of such licensure shall be made directly from the state or jurisdiction licensing the third party logistics provider.**
- (2) An inspection report, as required by [IC 25-26-14-29](#), dated not more than five (5) years from the date of application for a license issued by:**
  - (A) the licensing authority in the state where the third party logistics provider is located; or**
  - (B) a third party inspection provider.**

**(d) Each applicant shall designate on the application an individual who shall serve as an agent of the applicant.**

**SECTION 6. All applicants who are now, or have been, licensed as a third party logistics provider or wholesale drug distributor in another state must submit verification of license status. This information must be sent by the state that issued the license directly to the board.**

**SECTION 7. (a) The following bodies are approved by the board as third party inspection providers pursuant to [IC 25-26-14-10.3\(5\)](#):**

- (1) Any state licensing authority having jurisdiction over the licensure of wholesale drug distributors or third party logistics providers.**
- (2) The federal Food and Drug Administration.**
- (3) The National Association of Boards of Pharmacy's Verified Accredited Wholesale Distributor.**

**(b) The board may approve other accrediting bodies on a case-by-case basis. Such bodies must demonstrate the ability to competently inspect third party logistics providers for the requirements set forth in [IC 25-26-14-30](#).**

SECTION 8. The board may inspect, or cause to be inspected, the establishment of an applicant or licensee pursuant to [IC 25-26-14](#).

SECTION 9. (a) The license of any licensee shall terminate if and when such licensee ceases legal existence. Any licensee who ceases legal existence or discontinues business shall notify the board within ten (10) days of ceasing legal existence of discontinuing business.

(b) No license or any authority conferred thereby shall be assigned or otherwise transferred. Any entity that assumes new ownership of a license shall make an application for licensure and meet all the requirements of this document. While an application is pending due to a change of ownership, the new owner may continue to operate under the license number of the previous owner.

SECTION 10. Licensees shall adhere to all drug storage, packaging, and shipping requirements according to any federal Food and Drug Administration regulations, including the Drug Supply Chain Security Act (21 U.S.C. 360eee et seq.).

SECTION 11. Licensees shall maintain records, for two (2) years, of the acquisition and distribution of legend drugs obtained, stored, or shipped, and contracts with any manufacturers, wholesale drug distributors, or other entities for which the licensee is providing third party logistics services. Such records shall be made available to the board upon request.

SECTION 12. Licensees shall maintain policies and procedures regarding the following and shall make them available to the board upon request:

- (1) All policies and procedures required by [IC 25-26-14-30](#).
- (2) Employee training in the handling, storage, and distribution of legend drugs.

SECTION 13. A third party logistics provider shall not purchase, trade, sell, warehouse, distribute, or transfer any legend drugs to, from, or on behalf of a person or entity that is not authorized by law to purchase, trade, sell, warehouse, or distribute legend drugs.

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